TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No. A-8370

In Re Application Of: **Nyle ELLIOTT et al**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/720,213	November 25, 2003	Manuel A. Mendez	20741	3763	4978

Invention: **SINGLE USE CATHETER**

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

☒ Applicant claims small entity status. See 37 CFR 1.27

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Dated: 2/23/2009

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Nyle ELLIOTT et al.

Serial No: **10/720,213**

Filed : **November 25, 2003**

For : **SINGLE USE CATHETER**

Group Art Unit: **3763**

Examiner: **Manuel A. Mendez**

APPLICANT'S APPEAL BRIEF
UNDER 35 U.S.C. §41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

(1) REAL PARTY IN INTEREST

The real party in interest is Oakington Corporation, the assignee of the application.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

(3) STATUS OF CLAIMS

Claim 1-4, 7 and 8 are pending and stand rejected. The rejection of these claims is appealed. Claims 5 and 6 are cancelled.

(4) STATUS OF AMENDMENTS

A Response/Request for Reconsideration was filed on July 16, 2008. A final office action was mailed on December 26, 2008 rejecting the arguments set forth in the response.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The catheter has a balloon 26 inflated through a lumen 22. A one-way valve 32 in the inflation lumen allows inflation of the balloon, but prevents deflation. A one-way valve is a well-known term in the art for a valve allowing flow in one direction but preventing flow in the opposite direction. As explained in the second to last sentence on page 4 of the specification, the lumen must be cut in order to deflate the balloon. This ensures that the catheter may only be used once, which is a critical feature for hygienic reasons.

Claim 1 recites a single use catheter depicted in Figure 1, the only figure. The catheter has a lumen 20 having a proximate end and a distal end. An inflatable cuff 26 surrounds the lumen, the lumen having a first conduit 22 and second conduit 24, the first conduit in fluid communication with the inflatable cuff. The second conduit 24 is in fluid communication with the proximate end of said lumen. A port is at an end of said first conduit, and a one-way valve 32 in the port. The one-way port allows inflation of the cuff but does not allow deflation so that the first conduit must be cut to deflate the cuff, as described in the second to last sentence on page 4 of the specification.

Claim 7 recites a single use catheter depicted in Figure 1 having a first conduit 22 having a proximate end and a distal end and a second conduit 24 having a proximate end and a distal end, the second conduit parallel to the first conduit. An inflatable

cuff 26 surrounds the first and second conduits. The first conduit 22 is in fluid communication with said inflatable cuff 26, and a one way valve 32 at said distal end of said first conduit allows inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff, as described in the second to last sentence on page 4 of the specification.

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-4, 7 and 8 rejected as obvious over US 4,547,187 (Kelly), US 6,811,559(Thorton), US 6,682,508(Meythaler et al.), US 5,293,875(Stone) in further view of US 3,860,007(Binard et al.) and US 3,818,903 (Bleecker). The Examiner relies upon Thorton for disclosing hydrophobic tips, Meythaler et al. for disclosing the use of filters with infusion ports, Stone for the use of hydrophobic and charcoal filters in combination with filters. Further, Binard et al. is said to demonstrate the conventionality of severing a proximal section of a catheter shaft when an inflation lumen is obstructed and finally bleecker shows a ballon catheter having aone-way valve in fluid communication with an inflatable cuff or balloon. The Examiner alleges that the features taught by these five patents can be combined with the disclosure of Kelly to render the claims obvious in view of the "conventionality of applicant's enhancement." Finally, the Examiner states, "there are a finite number of valve designs in the art. Accordingly, for a person of ordinary skill in the art, it would have been obvious to try, different types of one-way valves…"

(7) ARGUMENT

The invention utilizes a one-way valve that allows inflation of the cuff but necessitates cutting of the catheter to deflate the cuff. This is discussed at, inter alia, the last sentence of the Summary of the Invention and the last two sentences on page 4. The limitation is clearly set forth in the claims. The term "one-way valve" is a well-known term in the art and the prior art applied by the Examiner does not disclose this feature.

Kelly discloses a catheter having a balloon 30 which is inflated through a port having a valve 20 best seen in Figures 6 and 7. This valve is not a one-way valve as it allows inflation and deflation of the balloon as explicitly stated in column 4, lines 37-38, which states "The valve 20 can be inflated and deflated directly with a hypodermic syringe 40 ...." The patent also discloses a valve 52 which operates in the same manner, but uses a standard Luer tip syringe without a needle. As stated in column 5, lines 43-45, when discussing valve 52, "When the balloon is to be deflated, the tip is again inserted until it opens the slit whereupon the air is released into the syringe."

Kelly does not disclose the one-way port disclosed and claimed in the application and Binard does not cure this deficiency. Binard discloses a catheter with a safety deflation means where the balloon *may* be deflated through the deflation movement by severing the catheter shaft adjacent its proximal end when the inflation movement is obstructed. But Binard et al. does not disclose a one-way port allowing inflation but preventing deflation through the port. Column 2, lines 39-42 discloses "... an inflation lumen extending between the inside of the balloon and adjacent the proximal end of the shaft, and valve means for controlling inflation and deflation of the balloon." Both Kelly

and Binard et al. disclose two-way valves, allowing both inflation and deflation of the balloon and therefore no prior art, taken alone or in combination, discloses or suggests the limitations in claims 1 and 7 regarding a one-way port preventing deflation of the balloon and necessitating cutting of the catheter for removal and ensuring its single use and avoiding reuse contamination.

The distinction between a catheter with a two way valve, such as Kelly and Binard et al., and a one way valve, as the invention, is a direct result of their respective functions. The catheters disclosed by both Kelly, a cholangiography inserted in a bile duct, and Binard, a urinary drainage catheter, are designed to be reused. The catheter of the invention, a rectal catheter, cannot be adequately sterilized to be used more than once. The one way valve requires the catheter be cut for removal and makes it impossible to be reused. The use of the catheter dictates the use of a one way valve to guarantee the single use of the catheter to preserve medical hygiene. Such concerns are not present in the prior art cited by the Examiner and explain their use of a two one valve. The two way valve allows deflation of the balloon without destroying the catheter, enabling their reuse. The deflation of the balloon through the valve is explicitly disclosed by both Kelly and Binard.

Both independent claims 1 and 7 recite a one-way valve allowing inflation of the cuff, but not allowing deflation, so that the conduit leading to the balloon must be cut to deflate the cuff. The first conduit leads to the cuff. This limitation is clearly not disclosed or suggested by Bleecker. The use of the valve, which does not allow deflation and requires cutting of the conduit, prevents the reuse of the catheter. Only by cutting the catheter, rendering the catheter non-useable, can the catheter be removed from the patient. In contrast, Bleecker clearly states at column 3, lines 7-11, that "When it is desired to remove the catheter, the valve opening device is manipulated to insert the prod into the end of the valve, against the end of the valve stem (which is usually grooved or ridged) to open the valve and permit fluid to escape. As the balloon deflates to an extent permitting removal of the catheter, the fluid is collected in the auxiliary reservoir with no possibility of spillage." Clearly, the valve allows deflation of

the cuff and the catheter may be reused. This is not possible with the invention. While Binard may disclose the severing of a catheter shaft when inflation movement becomes obstructed, it has no disclosure of a valve that allows inflation but does not allow deflation, requiring the cutting of the catheter to allow removal.

The cited art, taken alone or in combination, does not meet the express limitations of the claim. It is respectfully requested that the rejection be withdrawn and the application allowed.

The remaining patents are cited for features separate from the one-way valve and do not cure the deficiencies noted above.

It is respectfully requested that the rejections be overturned and the application allowed to issue.

Respectfully submitted,

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CLAIMS APPENDIX

1. A single use catheter, comprising:

a lumen having a proximate end and a distal end,

an inflatable cuff surrounding said lumen,

said lumen having a first and second conduit,

said first conduit in fluid communication with said inflatable cuff,

said second conduit in fluid communication with said proximate end of said lumen,

a port at an end of said first conduit, and

a one-way valve in said port, said one-way port allowing inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff.

2. The single use catheter of claim 1, further comprising a syringe attached to said port.

3. The single use syringe of claim 1, further comprising a hydrophobic filter tip on said lumen proximate end.

4. The single use syringe of claim 1, further comprising a charcoal filter in said second conduit.

7. A single use catheter, comprising:

a first conduit having a proximate end and a distal end,

a second conduit having a proximate end and a distal end, said second conduit parallel to said first conduit,

an inflatable cuff surrounding said first and second conduits,

said first conduit in fluid communication with said inflatable cuff, and

a one way valve at said distal end of said first conduit, said one-way port allowing inflation of said cuff but not allowing deflation whereby said first conduit must be cut to deflate said cuff.

8. The single use syringe of claim 7, further comprising:

a port at said first conduit distal end, and

a syringe attached to said port.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None